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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,546	10/30/2003	David W. Wynn	MCP-5015	7575

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,546	WYNN ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-16,18-22,25-27,29-31,34 and 36-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-16,18-22,25-27,29-31,34 and 36-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/1/08 & 8/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 5/20/08

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 7/1/08 and 8/14/08 were filed after the mailing date of the Specification on 10/20/03. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 13-16, 18-22, 25-27, 29-31, and 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Shah et al (USPN 6,126,969 hereafter '969) in view of Paradissis et al (USPN 5,133,974 hereafter '974) and Hsaio et al (USPN 5,885,616 hereafter '616). The claims are drawn to a dosage form comprising an immediate release and sustained release portion, where the dosage from has a liquid vehicle forming a liquid suspension.

The '969 patent teaches a dosage form comprising an immediate release portion and an extended releasing portion (abstract). The dosage from comprises sweeteners and other

excipients (col. 7, lin. 15-30). The extended release portion comprises coated core particles where the coating comprises an enteric polymer (col. 5, lin. 15-20; examples). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lin. 40-58). The active agents include various well-known drugs including acetaminophen (tables). Acetaminophen is well known pain relieving compound and is administered to patients in need thereof. The acetaminophen is present in each phase in a concentration of approximately 41.5 % (table 2). Another embodiment of the invention has the coated particles in a concentration of approximately 20.79% (table 1). The formulation comprises polyethylene glycol (Table 1 and 2). Regarding the therapeutic effect of the dosage from, it is the position of the Examiner that such limitations are inherent features of the composition. Regarding the liquid suspension limitation, the '969 patent is suggestive that the formulation can be dispersed in water in order to form a suspension (col. 4, lin. 15-17). The reference is however is not explicit about the exact structure of the liquid suspension; it is the position of the Examiner that the concentrations would be similar to those of the controlled release formulation. It is the position of the Examiner that these concentrations represent an optimization of ranges and are not inventive barring a showing of unexpected results.

The reference is silent to the ratio of the water insoluble polymer relative to the enteric polymers recited in the instant claims. This ratio is well within the level of skill in the art as seen in the '974 patent. The '974 patent discloses a combination extended/immediate release formulation comprising a mixture of immediate release drug particle combined with coated sustained release drug particles (abstract). The drugs include NSAID such as naproxen and indomethacin (col. 4, lin. 35). The immediate release particles comprise 0-50 % of the

formulation while the coated extended release particles make up the remainder (col. 8, lin. 5-25). The coatings for the extended release particles include a mixture of film forming polymers such as cellulose acetate and ethylcellulose while enteric polymers such as acrylic and methacrylic acid copolymers (col. 7, lin. 1-10). The ratio of film forming polymers to enteric polymers is 0.14:0.74 within the limits of the instant claims (examples). The combination formulation has a sustained release from 12-24 hours (examples). It would have been obvious to combine the film forming and enteric polymers in the ratios of the '974 patent since they teach the combination of similar polymers for the purposes of sustaining release of the active agent.

The '969 patent discloses the use of polyacrylic and methacrylic copolymers such as those sold under the name Eudragit, yet is silent to the specific polymers of the instant claims. These polymers are well known in the art and can be found in the '616 patent. The '616 patent discloses a dosage form comprising an immediate release drug portion and a controlled release drug portion (abstract). The drug includes acetaminophen (col. 5, lin. 15-20). The sustained release portion comprises multiple polymers, including an enteric polymer and an insoluble polymer (col. 6, lin. 35-55). The insoluble polymers include cellulose ethers, esters and acrylic resins such as Eudragit RL, and RS (poly (methacrylic acid, methyl methacrylate) in a weight ratio of 1:2 (col. 6, lin. 40-44). The enteric polymers include acrylate polymers such as Eudragit L and S (poly (methacrylic acid, methyl methacrylate) in a weight ratio of 1:1) (col. 6, lin. 50-54). The ratio of water insoluble polymer to enteric polymer in the sustained release layer is 28:5, or 5.6:1 well within the limits of the instant claims. The second drug component comprises from 5-30% of the total dosage from (col. 9, lin. 11-15). The active ingredient is present in the first or second compartments in a concentration as low as 70%, where the ratio of the first to

second drug compartments measure 4:1 to 1:4 by weight percentage (example 1, col. 8, lin. 28-34). The dosage form release up to 24 hours (TABLE IV-VII). The reference establishes the level of skill in the art regarding coating a sustained release portion f dosage form with specific polymethacrylic copolymers.

Regarding the pKa of the at least one active agent contained in the sustained release particles and its relation to the pH of the suspension it is the position of the Examiner that the prior art inherently meet s this limitation. It is the position of the Examiner that these limitations are merely functional limitations that are inherent to the combination formulation of the instant claims. The presented combination of prior art references meets the compositional limitations of the instant claims by discloses a suspension comprising both immediate release and coated sustained release particles where the particles comprising a combination of both hydrophilic film forming polymers and enteric polymers. The pKa and its relationship to the pH of the suspension is an inherent feature that cannot be separated from the components of the instant claims. As such since the prior art discloses a formulation meeting each of the compositional limitations it must also meet the functional limitations inherently.

With these things in mind it would have been obvious to combine the teachings and suggestions of the teachings and suggestions of the prior art in order to provide a stable liquid suspension. It would have been obvious to modify the ratio of polymers in the extended coating of the '969 patent as seen in the '974 patent in order to provide an improved and prolonged release of the extended release portions. It would have been obvious to include the specific polymers of the '616 patent since the '969 and '616 patents provide similar compounds for coating extended release portions. It would have been obvious to combine the teachings and

suggestions of the prior art with an expected result of a stable controlled release formulation useful in treating pain.

Response to Arguments

Applicant's arguments with respect to claims 13-16, 18-22, 25-27, 29-31, 34 and 36-46 have been considered but are moot in view of the new ground(s) of rejection. However the '969 patent discloses a combination immediate release and sustained release particulate formulation that can be dissolved in water to form a suspension. The sustained release particles comprise water insoluble polymers and enteric polymers in their coatings and acetaminophen is disclosed as a useful pain reliever. The '616 patent discloses a combination dosage from where the sustained release portion has two polymers in the coating. These disclosures continue to obviate the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 7:00-4:30; every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618